

# PATENT COOPERATION TREATY

From the  
INTERNATIONAL SEARCHING AUTHORITY

To:

see form PCT/ISA/220

## PCT

### WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY (PCT Rule 43bis.1)

Date of mailing  
(day/month/year) see form PCT/ISA/210 (second sheet)

Applicant's or agent's file reference  
see form PCT/ISA/220

**FOR FURTHER ACTION**  
See paragraph 2 below

International application No.  
PCT/CH2004/000094

International filing date (day/month/year)  
23.02.2004

Priority date (day/month/year)

International Patent Classification (IPC) or both national classification and IPC  
A61B17/17

Applicant  
SYNTHES AG CHUR

**1. This opinion contains indications relating to the following items:**

- ☒ Box No. I Basis of the opinion
- ☒ Box No. II Priority
- ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

**2. FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will usually be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA"). However, this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1b/s(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of three months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

**3. For further details, see notes to Form PCT/ISA/220.**

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**WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY**

International application No.  
PCT/CH2004/000094

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**Box No. I Basis of the opinion**

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1. With regard to the **language**, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.
  - ☐ This opinion has been established on the basis of a translation from the original language into the following language , which is the language of a translation furnished for the purposes of international search (under Rules 12.3 and 23.1(b)).
2. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:
  - a. type of material:
    - ☐ a sequence listing
    - ☐ table(s) related to the sequence listing
  - b. format of material:
    - ☐ in written format
    - ☐ in computer readable form
  - c. time of filing/furnishing:
    - ☐ contained in the international application as filed.
    - ☐ filed together with the international application in computer readable form.
    - ☐ furnished subsequently to this Authority for the purposes of search.
3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
4. Additional comments:

**WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY**

International application No.  
PCT/CH2004/000094

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**Box No. II Priority**

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1. ☒ The following document has not been furnished:

☒ copy of the earlier application whose priority has been claimed (Rule 43*bis*.1 and 66.7(a)).

☐ translation of the earlier application whose priority has been claimed (Rule 43*bis*.1 and 66.7(b)).

Consequently it has not been possible to consider the validity of the priority claim. This opinion has nevertheless been established on the assumption that the relevant date is the claimed priority date.

2. ☐ This opinion has been established as if no priority had been claimed due to the fact that the priority claim has been found invalid (Rules 43*bis*.1 and 64.1). Thus for the purposes of this opinion, the international filing date indicated above is considered to be the relevant date.

3. Additional observations, if necessary:

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**Box No. V Reasoned statement under Rule 43*bis*.1(a)(I) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

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1. Statement

Novelty (N)	Yes: Claims	3-9,12
	No: Claims	1,2,10,11
Inventive step (IS)	Yes: Claims	3-9,12
	No: Claims	1,2,10,11
Industrial applicability (IA)	Yes: Claims	1-12
	No: Claims	

2. Citations and explanations

**see separate sheet**

**Re Item V.**

**1. The following documents are referred to in this communication:**

D1 : US 5,766,174

**2. Independent claim 1**

The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claim 1 is not new in the sense of Article 33(2) PCT.

Document D1 discloses (the references in parenthesis applying to this document): "an intramedullary nail (20) with a distal end (80) for insertion into the medullary canal, a proximal end (60), a central axis and a generally rod-like shape over the hole length L, characterised in that said nail has three distinct locking sections, with at least one through-hole (32, 34) each for receiving locking screws whereby said three locking sections are separated from each other by two distinct intermediate sections having less through-holes per length unit than each of said locking sections" (see D1, col.3, l.41 to l.59).

**3. Dependent claims 2, 10, 11**

Dependent claims 2, 10, 11 are also known from D1, which further describes, an intramedullary nail (20) characterised in that said distinct intermediate sections have no through-holes (claim 2). The through hole (36) which is located nearest to said distal end (80) has a distance  $L_D$  to said distal end in the range of  $0,01 L < L_D < 0,38 L$  (claim 10). The through hole (32) which is located nearest to said proximal end (60) has a distance  $L_P$  to said proximal end in the range of  $0,01 L < L_P < 0,70 L$  (claim 11) (see D1, fig.4 and col.4, l.42 to l. 58)

**4. Dependent claims 3-9, 12**

Document D1, which is considered to represent the most relevant state of the art, discloses an intramedullary nail (20) having a cylindrical proximal portion and a rectangular distal portion.

The subject-matter of independent claim 3-9, 12 differs from the disclosure of D1 in that it contains further an isthmus locking section with a length of  $0,08 L < L_7 < 0,15 L$

The problem to be solved by the present invention may therefore be regarded as :  
"how to provide an intramedullary nail which can be adapted to various types of fractures".

The solution to this problem, proposed in claims 3-9, 12 of the present application, is to provide an intramedullary nail comprising three distinct locking sections which reduce the degree of freedom between the nail diameter and the intramedullary canal of the bone due to its isthmus locking section (see also the description p.5, §.3 to p.6, §. 1 and Figs. 2-5). Hence, the solution provided by the present application, to solve the problem to avoid the possibility of "play" in the system, was not obvious for the person skilled in the art.

**5. The following defects were observed:**

Contrary to the requirements of Rule 5.1(a)(ii) PCT, the relevant background art disclosed in the document D1 is not mentioned in the description, nor is this document identified therein.